

Message Text

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ORIGIN HEW-06

INFO OCT-01 ARA-10 ISO-00 OES-05 RSC-01 MED-03 /026 R

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ARA/MEX:JKEANE

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R 260011Z NOV 74

FM SECSTATE WASHDC

TO AMCONSUL TIJUANA

INFO AMEMBASSY MEXICO

UNCLAS STATE 260129

E.O. 11652: /A

TAGS: ETRD, EIND, TBIO, MX

SUBJ: DRUG RECALL - LABELING MIX-UP

1. FDA ADVISES THAT ALLERGEN PHARMACEUTICALS, 2525 DUPONT DRIVE, IRVINE, CALIFORNIA 92664 (CONTACT WILLIAM R. MULLEN, DIRECTOR OF QUALITY ASSURANCE, AREA CODE 714 833-8892) IS RECALLING PREFRIN - Z, LOTS NO. J0707, J1421, J1461, J1671, K0149, K0739, K0740, K0867, K0877, K1328, K1468 TO THE CONSUMER LEVEL.

2. DUE TO GANG PRINTING AND INADEQUATE CONTROLS, AN UNKNOWN NUMBER OF PREFRIN - Z UNIT CARTONS WERE MIXED WITH A LARGE NUMBER OF OPHTHETIC UNIT CARTONS. THIS RESULTED IN AN UNKNOWN NUMBER OF OPHTHETIC BOTTLES AND OPHTHETIC INSERTS BEING PACKAGED INTO UNIT CARTONS LABELED AS PREFRIN - Z. BOTH PRODUCTS ARE OPHTHALMIC SOLUTIONS IN 15 CC. BOTTLES; AND WITH UNIT CARTONS OF THE SAME SIZE AND COLOR COMBINATIONS (BLUE AND BLACK CARD-BOARD BOXES). PREFRIN - Z IS AN OTC DRUG USED AS A LUBRICATING ASTRINGENT AND DECONGESTANT FOR MINOR EYE IRRITATIONS WHEREAS OPHTHETIC IS AN RX DRUG (PROPARACAINE HYDROCHLORIDE 0.5 PERCENT) USED AS AN OPHTHALMIC ANESTHETIC.

3. THE PREFRIN - Z UNIT CARTONS BEING RECALLED ARE LABELED IN UNCLASSIFIED

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PART: ALLERGEN/LUBRICATING ASTRINGENT/DECONGESTANT, PREFRIN - Z,

LIQUIFILM OPHTHALMIC SOLUTION/1/2 FLUID OUNCE, STERILE, 15 ML./ACTIVE INGREDIENTS: ZINC SULPHATE 0.25 PERCENT, PHENYLE-PHRINE HYDROCHLORIDE 0.12 PERCENT LIQUIFILM (POLYVINYL ALCOHOL, 1.4 PERCENT).

4. THE CARTONS MAY BE LOCATED IN THE NORMAL PREFRIN - Z STORAGE AREA, OR MAY BE INTERMIXED WITH OPHTHETIC IN THE OPHTHETIC STORAGE AREA WITH THE OPHTHETIC UNIT CARTONS, OR MAY BE INTERMIXED WITH OPHTHETIC IN CLEAR CELLO SHRINK PACKS OF 12 INDIVIDUAL UNITS.

5. THE FIRM DISTRIBUTED 139,815 UNITS FROM AUGUST 1973 THROUGH 9/24/74. THESE UNITS REPRESENT TOTAL DISTRIBUTION OF THE 11 LOTS EXCEPT FOR 4,487 UNITS OF LOT K-1468. THE FIRM IS CONTINUING TO DISTRIBUTE THE REMAINDER OF LOT K-1468 AS THIS LOT HAS BEEN CHECKED. THE FIRM ESTIMATES THAT 10 PERCENT OF THE CUSTOMERS ARE WHOLESALERS WHO RECEIVED 50 PERCENT OF THE PRODUCT. 90 PERCENT ARE DIRECT CUSTOMERS THAT RECEIVED THE REMAINING 50 PERCENT OF THE PRODUCT.

6. FOREIGN CONSIGNEES AS FOLLOWS:

BOTICA TOREO, BLVD. ACQUA CALIENTE 188, TIJUANA,
BC, MEXICO

BOTICA LA DIVINA PROV., CALLE 3RD 218 ORIENTE, TIJUANA,
MEXICO

FARMACIA MEXICANA, 3RA Y CONSTITUCION, TIJUANA, BC, MEXICO

FARMACIA OSCARS, #3, RUIZ #475, ENSENADA, BC, MEXICO

FARMACIA CASTRO #1, ENSENADA, BC, MEXICO

7. POST IS REQUESTED TO ASCERTAIN WHETHER FOREIGN CONSIGNEES HAVE BEEN INFORMED OF DETAILS OF RECALL AND THOSE CONSIGNEES WHO HAVE RECEIVED MISLABELED PRODUCTS SHOULD RETURN SAID PRODUCT TO FIRM. INGERSOLL

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: DRUGS, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 26 NOV 1974
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1974STATE260129
Document Source: CORE
Document Unique ID: 00
Drafter: DHEW/FDA:JRWEINROTH, MD
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D740342-0546
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1974/newtext/t19741111/aaaaaizx.tel
Line Count: 95
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: MorefiRH
Review Comment: n/a
Review Content Flags:
Review Date: 13 NOV 2002
Review Event:
Review Exemptions: n/a
Review History: RELEASED <13 NOV 2002 by maustmc>; APPROVED <19-Nov-2002 by MorefiRH>
Review Markings:

Declassified/Released
US Department of State
EO Systematic Review
30 JUN 2005

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: DRUG RECALL - LABELING MIX-UP
TAGS: ETRD, TBIO, MX, ALLERGEN PHARMACEUTICALS
To: TIJUANA
Type: TE
Markings: Declassified/Released US Department of State EO Systematic Review 30 JUN 2005